K112152

NOV - 9 2011

SECTION 5. 510(k) SUMMARY
for
Cercon ht

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: November 8, 2011

2. Device Name:

- Proprietary Name: Cercon ht
- Classification Name: Porcelain powder for clinical use
- CFR Number: 21CFR 872.6600
- Device Class: II
- Product Code: EIH

3. Predicate Device:

Cercon Base, K013230 and K051462

4. Description of Device:

Cercon ht is a ceramic composed of partially sintered yttria stabilized zirconia powder (Y-TZP). It is supplied to the dental laboratory as a blank and then processed in the dental-laboratory by machining and subsequent sintering to full density. It can be veneered with a dental veneering ceramic or can be used as anatomically shaped full-contour crown or bridge without veneering. It is designed for anterior and posterior locations as a substructure (framework) for single-tooth or bridge type restorations. It can also be used for the preparation of telescopic primary crowns.

5. Indications for Use:

Cercon® ht is indicated in the anterior and posterior segments for:

- crowns
- telescopic primary crowns
- multi-unit bridges (with no more than two pontics between abutment crowns)

Cercon® ht can be used as a substructure (framework) which is then veneered with a dental veneering ceramic or can be used for full-contour application (without veneering) as well. In the case of telescopic primary crowns the substructure is not veneered.

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6. Description of Safety and Substantial Equivalence:

Technological Characteristics.
Cercon ht is an oxid-based ceramic composed of partially sintered yttria stabilized zirconia powder indicated for crown and bridge restorations. Cercon ht is a ceramic material according to ISO 6872 Type II / Class 6. The strength of this material is similar to that of dental alloys containing high gold. The components of Cercon ht have been used in the predicate devices and were found safe for dental use. The device has the same technological characteristics and composition as the predicate device. The main difference is the extended indication for use including bridges with a wider span, the use as full contour crown or bridge, the use for the preparation of telescopic primary crowns.

Non-Clinical Performance Data.
Measurements of the physical characteristics showed that the material has the same mechanical (flexural strength) and chemical stability (solubility) as the predicate device.

Wear Tests showed that the abrasion of the unveneered material itself and of the antagonist teeth opposed to the material is significantly lower compared to conventional veneering porcelain.

Test of the fit of large bridges showed that they are comparable to conventional metal cast frameworks.

Test of telescopic primary crowns showed that a good fitting accuracy and a good surface quality is achieved.

Clinical Performance Data.
Not applicable.

Conclusion as to Substantial Equivalence
The chemical components used in the material of Cercon ht and its technological characteristics are the same as in the predicate device. The substantial equivalence of the indications for use has been proven by bench tests and professional evaluations.

- The use of telescopic primary crowns has been evaluated with Cercon Base. As the physical properties of Cercon ht are similar to Cercon base (c.f. Section 12, Substantial Equivalent Discussion) it can be concluded that these results are valid for Cercon ht.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Helen Lewis
Director of Corporate Compliance & Regulatory Affairs
Dentsply International, Incorporated
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

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Re: K112152
Trade/Device Name: Cercon ht
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 29, 2011
Received: September 30, 2011

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112152

Device Name: Cercon ht

Indications for Use:

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- crowns
- telescopic primary crowns
- multi-unit bridges (with no more than two pontics between abutment crowns)

Cercon® ht can be used as a substructure (framework) which is then veneered with a dental veneering ceramic or can be used for full-contour application (without veneering) as well. In the case of telescopic primary crowns, the substructure is not veneered.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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